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| APPLICATION NO | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO | CONFIRMATION NO |
|----------------|-------------|----------------------|--------------------|-----------------|
| 10/001,684     | 10/25/2001  | David P. Katz        | AMBIINC.006A       | 3175            |

20995 7590 07/30/2002

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EXAMINER

PATTEN, PATRICIA A

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 07/30/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/001,684

Applicant(s)

Katz, D.

Examiner

Patricia Patten

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 4 6) ☐ Other: \_\_\_\_\_

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## **DETAILED ACTION**

Claims 1-15 are pending in the application and were presented for examination on the merits.

### ***Specification***

The disclosure is objected to because of the following informalities:

The Disclosure contains numerical references before each paragraph.

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claims 1-15 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a treatment for normalizing glucose levels, does not reasonably provide enablement for a treatment for polycystic ovary syndrome. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The factors to be considered in determining whether undue experimentation is required are summarized in *re Wands* 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir, 1988). The court in *Wands* states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.'" (*Wands*, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (*Wands*, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in

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the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. While all of these factors are considered, a sufficient amount for a *prima facie* case are discussed below.

Inventions targeted for human therapy bear a heavy responsibility to provide supporting evidence because of the unpredictability in biological responses to therapeutic treatments. The standard of enablement is higher for such inventions because effective treatments for disease conditions are relatively rare, and may be unbelievable in the absence of strong supporting evidence. Claims drawn to pharmaceutically acceptable compositions and to methods of administering compounds to humans generally require supporting evidence because of the unpredictability in biological responses to therapeutic treatments.

In the Instant case, Applicants have claimed a method for treating Polycystic ovary syndrome (POS) with a composition comprising chromium complexes. POS is a disease which afflicts about 3% of the female adult population. It is characterized by amenorrhea, hirsutism and obesity due to enlarged polycystic ovaries. Additionally, side effects of POS include chronic anovulation and infertility. Treatments for POS are scarce although some compounds such as human menopausal gonadotrophin and clomiphene citrate have provided relief for some symptoms of POS (All information taken from Vanderbilt Medical Center Online, accessed 7/17/02).

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Because the syndrome encompasses many secondary disease parameters, it appears difficult to treat and therefore alleged 'treatments' for POS are deemed unpredictable lacking considerable evidence to the contrary. Chromium was not known in the art for treating Polycystic ovary syndrome. Additionally, Chromium III complexes were found to promote chromosome damage in hamsters (Stearns et al. 1995). Thus, a claim to a treatment for POS would necessarily need to provide sufficient scientific evidence to substantiate such an assertion.

Applicants have provided one working example which includes one subject suffering from POS who was administered a composition comprising chromium picolinate, picolinic acid, guaifenesin and ibuprofen. Applicants teach that the subject displayed a decrease in body mass and improved lipid profile was observed after several weeks. First, it is noted that it is not known what the term 'decreased' means. Is this one pound or twenty pounds. It is further not known that 'improved lipid profile' means. Additionally, Applicants have not shown that other characteristics of POS were improved, namely, amenorrhea, hirsutism, anovulation and infertility as a few examples.

Thus, although Applicants have claimed a method for treating POS with compositions comprising chromium complexes, Applicants have only demonstrated that the composition of the Instant invention may have improved insulin and lipid levels, thus, not supporting the assertion that the compositions would treat the actual disease POS which is characterized by various secondary ailments. Due to the lack of

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guidance within the specification, as well as in the prior art regarding treating ailments associated with POS the skilled artisan would necessarily need to perform undue experimentation based on trial and error protocols without expectation of success.

*In re Fisher*, 427 F.2d 833, 166 USPQ 18 (CCPA 1970), held that

"Inventor should be allowed to dominate future patentable inventions of others where those inventions were based in some way on his teachings, since such improvements while unobvious from his teachings, are still within his contribution, since improvement was made possible by his work; however, *he must not be permitted to achieve this dominance by claims which are insufficiently supported and, hence, not in compliance with first paragraph of 35 U.S.C. 112*; that paragraph requires that scope of claims must bear a reasonable correlation to scope of enablement provided by specification to persons of ordinary skill in the art; in cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad enablement in the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific law; in cases involving unpredictable factors, such as most chemical reactions and physiological activity, scope of enablement varies inversely with degree of unpredictability of factors involved."

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Claims were examined on the merits for their enabling scope, namely, a method for decreasing lipid levels and improving insulin levels in a subject in need thereof.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 recites 'chromium yeasts.' This term is not found in the art and the Examiner has trouble ascertaining the meets and bounds of this term. It is believed that Applicant means that these are yeast which contain chromium, but the Examiner is not sure (it could mean chromium complexes derived from yeast - and if so, what complexes are these?).

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:



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(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

Claims 1-8 and 10-15 are rejected under 35 U.S.C. 102(e) as being anticipated by de la Harpe et al. (US 5,980,905). Claims 1-8 and 10-15 were examined for the enabled scope of the claim: a method for decreasing lipid and glucose levels via administration of a chromium complex, wherein said complex comprises a species of chromium such as chromium picolinate, wherein the composition further contains constituents such as a chelating agent (picolinic acid or nicotinic acid), a mucolytic such as guaifenesin, a salicin-containing herb such as *Boswellia serrata*, a cox inhibitor such as acetaminophen. Claims are further drawn to wherein the complex is administered in a ratio of between about 1:10 and about 10:1, wherein the effective dose is between about 50 and about 10,000 micrograms, wherein the composition is in a carrier such as a microbead, and wherein said microbead is a microcrystalline and the chromium complex is coated on the beadlet.

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It was known in the art that chromium complexes such as chromium polynicotinate lowered overall glucose and blood lipid levels. De la Harpe et al. (US 5,980,905) disclosed a composition identical to the composition present in the Instant method claims for lowering blood glucose levels and serum lipid levels (Abstract, and Claims 1-19). Because each dependant claim further limits the independent claim, claims 1-7 disclose the composition of the Instantly claimed method.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Patricia Patten, whose telephone number is (703)308-1189. The examiner can normally be reached on M-F from 9am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

A handwritten signature in black ink, appearing to be "C. R. Tate", written in a cursive style.

CHRISTOPHER R. TATE  
PRIMARY EXAMINER